DEC 2 1 2001

K013371

510(k) Summary
for
UBiT-IR300 Infrared Spectrometry System

1. SPONSOR

Otsuka Pharmaceutical Co., Ltd.
2-9, Kanda Tsukasa-cho, Chiyoda-ku
Tokyo 101-8535 Japan

Contact Person:
Japan: Hideji Nonomura
Telephone: 81-88-665-2126

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Date Prepared: December 17, 2001

2. DEVICE NAME

Proprietary Name:	UBiT-IR300 Infrared Spectrometry System
Common/Usual Name:	Infrared Spectrometry System
Classification Name:	Colorimeter, Photometer, or Spectrophotometer for Clinical Use

For use of the UBiT-IR300 System in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection, the following are also applicable:

Common/Usual Name:	Analysis System for Use with ^{13}C-Urea Breath Test
Classification Name:	Urea Breath Test

3. Predicate Devices

- ABCA-NT Gas Isotope Ratio Mass Spectrometer (GIRMS) System
  Europa Scientific Limited
  K974322

4. DEVICE DESCRIPTION

The UBiT-IR300 Infrared Spectrometry System is a compact analyzer designed for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori*. The UBiT-IR300 measures absorption of breath gas by calculating the ratios of $^{13}CO_2/^{12}CO_2$ for a reference breath gas and a sample breath gas. The difference between the ratios for the reference and sample breath gases is calculated to obtain the final measurement result, which is reported as $\Delta^{13}CO_2$ and expressed as delta per mil (‰) or Delta Over Baseline (DOB).

The System consists of the following components:

- UBiT-IR300 Infrared Spectrophotometer
- UBiT-AS10 Autosampler
- Otsuka Breath Collection Bags

5. INTENDED USE

The UBiT-IR300 Infrared Spectrometry System is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The system consists of the UBiT-IR300 Infrared Spectrophotometer, the UBiT-AS10 Autosampler, and Otsuka Breath Collection Bags.

The UBiT-IR300 Infrared Spectrometry System is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The UBiT-IR300 System is suitable for use in both clinical laboratory and point-of-care settings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the UBiT-IR300 System and the ABCA-NT are general purpose instrument systems that are intended to measure changes in $^{13}CO_2$ content in breath CO_2 and have many potential applications. One of the applications for these systems is for use with commercially available ^{13}C-urea breath tests (^{13}C-UBT) for *H. pylori*. Meretek Urea Breath Test Collection Kits can be used in conjunction with either system and the required breath samples collected for analysis.

The UBiT-IR300 System includes specially designed breath collection bags that subjects blow into for collection of the breath samples. The ABCA-NT uses standard commercially available evacuated tubes for collection of breath samples.

The UBiT-IR300 and the ABCA-NT systems are similar in functional design but use different methods of gas measurement. The UBiT-IR300 uses an infrared spectrophotometer to analyze the gas samples, while the ABCA-NT uses a Gas Isotope Ratio Mass Spectrometer (GIRMS). The UBiT-IR300 is smaller and more compact than the ABCA-NT, and is specifically designed for on-site use. Both systems include an autosampler and a computer for data analysis and storage. The UBiT-IR300 computer is built into the analyzer, while the ABCA-NT has an external computer system.

7. PERFORMANCE TESTING

7.1 Nonclinical Testing

The UBiT-IR300 and UBiT-AS10 were tested to and comply with IEC 60601-1 and IEC 60601-1-2.

Reproducibility and carry-over studies were conducted on the UBiT-IR300 alone and with the UBiT-IR300 connected to the UBiT-AS10 Autosampler. These studies demonstrate that the UBiT-IR300 performs according to its specifications and there is negligible carryover.

7.2 Clinical Testing

A clinical study was conducted to evaluate the performance of the UBiT-IR300 Infrared Spectrometry System to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The multi-center, prospective study was designed to compare the UBiT-IR300 Infrared Spectrophotometer for measuring $^{13}CO_2$ enrichment in breath with the traditional Gas Isotope Ratio Mass Spectrometry (GIRMS) method. Subjects were recruited from four Physician Office Laboratory (POL) settings and one clinical laboratory setting. Subjects underwent a standard urea breath test (UBT) which is used for the detection of *Helicobacter pylori* (*H. pylori*) infection. Analyses of breath samples were performed using both the UBiT-IR300 Infrared Spectrophotometer and GIRMS methods. The number of evaluable subjects was 257 for the combined POL sites and 63 for the clinical laboratory site with a total of 320 evaluable subjects across all participating sites.

The primary endpoint was the percent agreement of the UBiT-IR300 results as compared to the result generated by the GIRMS method using a cut-off value of 2.4 Delta Over Baseline (DOB). Results for all POLs plus the clinical laboratory are as follows:

% Overall Agreement:	99.06% [95% CI: (97.35, 99.74)]
% Positive Agreement:	98.29% [95% CI: (94.26, 99.70)]
% Negative Agreement:	99.51% [95% CI: (97.49, 99.97)]

As a secondary endpoint, paired Delta Over Baseline (DOB) values were analyzed directly in order to determine the extent to which the methods were linearly related and the degree to which they were correlated. Comparison of the paired DOB values demonstrates that the two methods give results which are very highly correlated ($r>.99$) and appear to be linearly related to one another. The data suggest that the regression lines pass through the origin with a slope very near one.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Otsuka Pharmaceutical Co., Limited
c/o Ms. Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

DEC 2 1 2001

Re: k013371
Trade/Device Name: UBiT-IR300 Infrared Spectrometry System
Regulation Number: 21 CFR 862.2300, 866.3110
Regulation Name: Colorimeter, Photometer, Spectrophotometer for Clinical Use, Urea Breath Tests
Regulatory Class: Class I
Product Code: JJQ, MSQ
Dated: October 9, 2001
Received: October 11, 2001

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013371

Device Name: UBiT-IR300 Infrared Spectrometry System

Indications For Use:
The UBiT-IR300 Infrared Spectrometry System is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The system consists of the UBiT-IR300 Infrared Spectrophotometer, the UBiT-AS10 Autosampler, and Otsuka Breath Collection Bags.

The UBiT-IR300 Infrared Spectrometry System is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The UBiT-IR300 System is suitable for use in both clinical laboratory and point-of-care settings.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lucretia M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013371

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)